UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

JAMES & DORIS DAUGHERTY Plaintiffs, vs. XANODYNE PHARMACEUTICALS, INC. Defendants,	CASE NO. JUDGE **C O M P L A I N T** DEMAND FOR JURY TRIAL

Plaintiffs, by their attorneys, and on behalf of themselves, upon information and belief, at all times hereinafter mentioned, alleges as follows:

JURISDICTION

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds $75,000.00, exclusive of interest and costs, and because Defendant, XANODYNE PHARMACEUTICALS, INC. is incorporated and has its principal places of business in states other than the state in which the named Plaintiff resides.

2. This Court has supplemental jurisdiction over the remaining common law and state claims pursuant to 28 U.S.C. § 1367.

3. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to Plaintiff's claims occurred, in part, in the Northern District of Ohio.

NATURE OF THE CASE

4. This action is brought on behalf of Plaintiffs, JAMES DAUGHERTY, who was prescribed, purchased and correctly used Darvocet, also known generically as Propoxyphene Napsylate and Acetaminophen and DORIS DAUGHERTY, spouse of Plaintiff JAMES DAUGHERTY.

5. Defendant, XANODYNE PHARMACEUTICALS, INC (hereinafter referred to as "Defendant") designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Darvocet for use as a prescription pain management medication.

6. Defendant concealed their knowledge of Darvocet's defects, from Plaintiff, the Food and Drug Administration (hereinafter referred to as "FDA"), the public in general and/or the medical community specifically.

7. When warning of safety and risks of Darvocet, Defendant negligently and/or fraudulently represented to the medical and healthcare community, the FDA, to Plaintiff and the public in general, that Darvocet had been tested and was found to be safe and/or effective for its indicated use.

8. These representations were made by Defendant with the intent of defrauding and deceiving Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical community in particular, to recommend, dispense and/or purchase Darvocet for use as a

prescription pain management medication, all of which evinced a callous, reckless, willful, depraved indifference to health, safety and welfare of the Plaintiff herein.

9. Defendant negligently and improperly failed to perform sufficient tests, if any, concerning Darvocet's potential to cause cardiotoxicity and, more specifically, potentially fatal cardiac arrhythmias, forcing Plaintiff, and his physicians, hospitals, and/or the FDA, to rely on safety information that applies to other prescription pain management medications, which does not entirely and/or necessarily apply to Darvocet.

10. As a result of the defective nature of Darvocet, those persons who use and/or used and relied on Darvocet have suffered and/or are at a greatly increased risk of serious and dangerous side effects including, *inter alia*, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

11. Plaintiff herein has sustained certain of the above health consequences due to his use of Darvocet

12. Defendant concealed its knowledge of the defects in its product from the Plaintiff, and his physicians, hospitals, pharmacists, the FDA, and the public in general.

13. Consequently, Plaintiff seeks compensatory damages as a result of his use of Darvocet, which has caused, may cause, and/or will continue to cause Plaintiff to suffer and/or be at greatly increased risk of serious and dangerous side effects including heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as

other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

PARTY PLAINTIFF

14. Plaintiff, JAMES DAUGHERTY, is a natural person and is a resident of the State of Ohio.

15. Prior to February 2007, plaintiff, JAMES DAUGHERTY, did not have a pre-existing cardiac history and had never suffered a cardiac arrhythmia.

16. Plaintiff, JAMES DAUGHERTY, was prescribed Darvocet for pain management in or about 1993.

17. As result of using Defendant’s drug Darvocet, Plaintiff JAMES DAUGHERTY, was caused to suffer cardiovascular injuries and cardiac arrhythmias, including but not limited to, atrial fibrillation in or about February 2007.

18. Plaintiff, JAMES DAUGHERTY used Darvocet in the manner in which it was prescribed to him at or about the time he suffered cardiovascular injuries and arrhythmias, including but not limited to, atrial fibrillation.

19. In order to treat his arrhythmia and life threatening cardiac condition, plaintiff, JAMES DAUGHERTY, underwent painful electrocardioversion.

20. Plaintiff, JAMES DAUGHERTY, was caused to sustain severe, permanent and life threatening personal injuries, pain, suffering, emotional distress, lifelong fear of premature death and the need for continued lifelong cardiac monitoring, treatment and medications.

21. The injuries and damages sustained by Plaintiff, JAMES DAUGHERTY, were caused by Defendant's drug Darvocet.

PARTY DEFENDANT

22. Upon information and belief, Defendant XANODYNE PHARMACEUTICALS, INC. was at all relevant times a corporation organized under the laws of the State of Kentucky, with its principal place of business located in the State of Kentucky.

23. Upon information and belief, at all relevant times Defendant XANODYNE PHARMACEUTICALS, INC. has transacted and conducted business in the State of Ohio and derived substantial revenue from interstate commerce.

24. Upon information and belief Defendant XANODYNE PHARMACEUTICALS, INC., expected or should have expected that its acts would have consequences within the United States of America, and Cortland, Ohio and within the confines of the Northern District of Ohio in particular and derived substantial revenue from interstate commerce.

25. Upon information and belief, at all relevant times Defendant XANODYNE PHARMACEUTICALS, INC. was in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute Darvocet for use as a prescription management medication

26. Upon information and belief, Defendant XANODYNE PHARMACEUTICALS, INC. is the holder of approved New Drug Application for Darvocet.

FACTUAL BACKGROUND

27. At all relevant times, Defendant was and remains in the business of and did design, research, manufacture, test, advertise, promote, market, sell, distribute, and/or have recently acquired the Defendant who has designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed Darvocet for use as a prescription pain management medication.

28. At all times relevant, Defendant focused its sales on pain management products including Darvocet because the area of pain management offers attractive commercial opportunities in significant markets in the United States, see http://www.xanodyne.com/strategy.asp (as of December 9, 2010).

29. At all times relevant, Defendant affirmatively decided not to take part in full discovery research of its products because Defendant believed that it was more beneficial for it to advance products quickly through abbreviated developmental pathways in order to decrease the time and cost of bringing a new drug to market, see http://www.xanodyne.com/strategy.asp (as of December 9, 2010).

30. By using a strategy of moving its products through the research and development process expeditiously Defendant believes it can reach its goal of becoming a leading integrated specialty pharmaceutical company that develops and commercializes new products for significant markets in pain management, http://www.xanodyne.com/strategy.asp (as of December 9, 2010).

31. In 2009, about 10 million people in the U.S. received prescriptions for Darvocet -related drugs according to the FDA.

32. Upon information and belief, Adverse Event ("AE") data maintained by the FDA indicates staggering, serious AEs, including, heart arrhythmias, atrial fibrillation, tachycardia, bradycardia, myocardial infarction, and/or sudden death.

33. Defendant ignored the correlation between the use of Darvocet and the increased risk of developing potentially fatal heart arrhythmias, despite the wealth of scientific and medical evidence available.

34. In June 2009, the European Medicines Agency ("EMEA") recommended that the marketing authorizations for Darvocet be withdrawn across the European Union for safety concerns.

35. Despite being petitioned by public interest groups to investigate whether Darvocet was linked to serious and potentially fatal heart arrhythmias, Defendant refused to do so until July 2009, when it was ordered by the FDA to conduct a safety study assessing unanswered questions about the effects of Darvocet on the heart.

36. Plaintiff, JAMES DAUGHERTY, experienced a potentially fatal cardiac arrhythmia as a result of taking Darvocet in February 2007.

37. The results of the study ordered by the FDA indicated that even when taken at recommended doses, Darvocet causes significant changes to the electrical activity of the heart. These changes, which can be seen on an electrocardiogram ("ECG" or "EKG"), can increase the risk for serious abnormal heart rhythms that have been linked to serious adverse effects, including sudden death.

38. On November 19, 2010, the FDA announced that Defendant, Xanodyne Pharmaceuticals, Inc., had agreed to halt all U.S. Marketing of Darvocet after it was

determined that the drugs benefits were outweighed by the risks associated with its use, specifically the potential of the drug to cause serious and potentially fatal heart arrhythmias.

39. The use of Darvocet creates unique and dangerous risks compared to other prescription pain management medications. These risks include, heart arrhythmias, myocardial infarction, and other adverse cardiovascular events, including sudden death.

40. The Defendant did not provide adequate warnings to doctors, the health care community and the general public about the increased risk of serious adverse events that are described herein and that have been reported by the medical community.

41. By reason of the foregoing, Plaintiff has developed dangerous side effects including, heart arrhythmias and other adverse cardiovascular events, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

42. Plaintiff has endured and continues to suffer the mental anguish and psychological trauma of living with the knowledge that he has sufferers serious and dangerous side effects including, heart arrhythmias and other adverse cardiovascular events, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

43. By reason of the foregoing, Plaintiff has been severely and permanently injured, including the risk of premature death, and will require more constant and continuous medical monitoring and treatment than prior to his use of Defendant's drug Darvocet.

FEDERAL REQUIREMENTS

44. Defendant had an obligation to comply with the law in the manufacture, design, and sale of Darvocet.

45. Upon information and belief, Defendant violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, *et seq*.

46. With respect to the prescription drug Darvocet, the Defendant, upon information and belief, has or may have failed to comply with all federal standards applicable to the sale of prescription drugs including, but not limited to, one or more of the following violations:

a. The prescription drug Darvocet is adulterated pursuant to 21 U.S.C. § 351 because, among other things, it fails to meet established performance standards, and/or the methods, facilities, or controls used for its manufacture, packing, storage or installation is not in conformity with federal requirements. See, 21 U.S.C. § 351.

b. The prescription drug Darvocet is adulterated pursuant to 21 U.S.C. § 351 because, among other things, its strength differs from or its quality or purity falls below the standard set forth in the official compendium for Darvocet and such deviations are not plainly stated on their labels.

c. The prescription drug Darvocet is misbranded pursuant to 21 U.S.C. §352 because, among other things, it's labeling is false or misleading.

d. The prescription drug Darvocet is misbranded pursuant to 21 U.S.C. §352 because words, statements, or other information required by or under authority of chapter 21 U.S.C. § 352 are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

e. The prescription drug Darvocet is misbranded pursuant to 21 U.S.C. §352 because the labeling does not bear adequate directions for use, and/or the labeling does not bear adequate warnings against use where its use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users.

f. The prescription drug Darvocet is misbranded pursuant to 21 U.S.C. §352 because it's dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

g. The prescription drug Darvocet does not contain adequate directions for use pursuant to 21 CFR § 201.5, because, among other reasons, of omission, in whole or in part, or incorrect specification of (a) statements of all conditions, purposes, or uses for which it is intended, including conditions, purposes, or uses for which it is prescribed, recommended or suggested in their oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drugs are commonly used, (b) quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions, (c) frequency of administration or application, (d) duration or administration or application, and/or (d) route or method of administration or application.

h. The Defendant violated 21 CFR § 201.56 because the labeling was not informative and accurate.

i. The prescription drug Darvocet is misbranded pursuant to 21 CFR § 201.56 because the labeling was not updated as new information became available that caused the labeling to become inaccurate, false, or misleading.

j. The Defendant violated 21 CFR § 201.57 by failing to provide information that is important to the safe and effective use of the drug including the potential of Darvocet cause and the need for regular and/or consistent cardiac monitoring to ensure that a potential fatal cardiac arrhythmia has not developed.

k. The Defendant violated 21 CFR § 201.57 because they failed to identify specific tests needed for selection or monitoring of patients who took the prescription drug Darvocet.

l. The Defendant violated 21 CFR § 201.57 because the safety considerations regarding the prescription drug Darvocet are such that the drug should be reserved for certain situations, and the Defendant failed to state such information.

m. The prescription drug Darvocet is mislabeled pursuant to 21 CFR § 201.57 because the labeling fails to describe serious adverse reactions and potential safety hazards, limitations in use imposed by it, and steps that should be taken if they occur.

n. The prescription drug Darvocet is mislabeled pursuant to 21 CFR § 201.57 because the labeling was not revised to include a warning as soon as there was reasonable evidence of an association of a serious hazard with the drug.

o. The Defendant violated 21 CFR § 201.57 because the labeling failed to list the adverse reactions that occur with the prescription drug Darvocet and other drugs in the same pharmacologically active and chemically related class.

p. The Defendant violated 21 CFR § 201.57 because the possibility that a patient could develop cardiac arrhythmias, while significantly more severe than the other reactions listed in the adverse reactions section, was not listed by Defendant before the other less serious adverse reactions on the labeling of the prescription drug Darvocet.

q. The prescription drug Darvocet is mislabeled pursuant to 21 CFR § 201.57 because the labeling does not state the recommended usual dose, the usual dosage range, and, if appropriate, an upper limit beyond which safety and effectiveness have not been established.

r. The prescription drug Darvocet violates 21 CFR § 210.1 because the process by which it was manufactured, processed, and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing, or holding of a drug to assure that it meets the requirements as to safety and have the identity and strength and meets the quality and purity characteristic that they purport or are represented to possess.

s. The prescription drug Darvocet violates 21 CFR § 210.122 because the labeling and packaging materials do not meet the appropriate specifications.

t. The prescription drug Darvocet violates 21 CFR § 211.165 because the test methods employed by the Defendant are not accurate, sensitive, specific, and/or reproducible and/or such accuracy, sensitivity, specificity, and/or reproducibility of test methods have not been properly established and documented.

u. The prescription drug Darvocet violates 21 CFR § 211.165 in that the prescription drug Darvocet fails to meet established standards or specifications and any other relevant quality control criteria.

v. The prescription drug Darvocet violates 21 CFR § 211.198 because the written procedures describing the handling of all written and oral complaints regarding the prescription drug Darvocet were not followed.

w. The prescription drug Darvocet violates 21 CFR § 310.303 in that the prescription drug Darvocet is not safe and effective for its intended use.

x. The Defendant violated 21 CFR § 310.303 because the Defendant failed to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds for suspending or withdrawing approval of the application to the FDA.

y. The Defendant violated 21 CFR §§310.305 and 314.80 by failing to report adverse events associated with the prescription drug Darvocet as soon as possible or at least within 15 days of the initial receipt by the Defendant of the adverse drugs experience.

z. The Defendant violated 21 CFR §§310.305 and 314.80 by failing to conduct an investigation of each adverse event associated with the prescription drug Darvocet, and evaluating the cause of the adverse event.

aa. The Defendant violated 21 CFR §§ 310.305 and 314.80 by failing to promptly investigate all serious, unexpected adverse drug experiences and submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA.

bb. The Defendant violated 21 CFR §§ 310.305 and 314.80 by failing to keep records of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse drug experiences.

cc. The Defendant violated 21 CFR §§ 310.305 and 314.80 by failing to identify the reports they submitted properly, such as by labeling them as "15-day Alert report," or "15-day Alert report follow up."

dd. The Defendant violated 21 CFR § 312.32 because they failed to review all information relevant to the safety of the prescription drug Darvocet or otherwise received by the Defendant from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not already been previously reported to the agency by the sponsor.

ee. The Defendant violated 21 CFR § 314.80 by failing to provide periodic reports to the FDA containing (a) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval, (b) an Adverse Reaction Report for each adverse drug experience not already reported under the Post marketing 15-day Alert report, and/or (c) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated).

ff. The Defendant violated 21 CFR § 314.80 by failing to submit a copy of published articles from scientific or medical journals along with one or more 15-day Alert reports based on information from the scientific literature.

47. Defendant failed to meet the standard of care set by the above statutes and regulations, which were intended for the benefit of individual consumers such as the Plaintiff, making the Defendant negligent *per se*.

FIRST CAUSE OF ACTION
PRODUCT DEFECT IN MANUFACTURE AND CONSTRUCTION
OHIO REVISED CODE § 2307.74

48. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth

herein and further alleges on information and belief as follows:

49. At all times relevant to this action, Defendant was the manufacturers and/or supplier of Darvocet products and/or their pharmaceutical ingredients, placing the prescription drug into the stream of commerce.

50. Defendant had a duty to manufacture, design, formulate, produce, create, make, construct, and/or assemble a pain medication that would conform to the chemical composition, formula, or performance standards of Defendant and would not cause users to suffer unreasonable, dangerous side effects such as heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death.

51. Defendant breached this duty to manufacture, design, formulate, produce, create, make, construct, and/or assemble a pain medication that would conform to the chemical composition, formula, or performance standards of Defendant in that Defendant knew or should have known its Darvocet products were defective and would cause its users to suffer severe side effects in consequence of using the Darvocet products. Defendant's Darvocet products did not function as intended and, or in the alternative, created a high risk of unreasonable, dangerous side effects; to wit: heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death.

52. The Darvocet products were expected to and did reach Plaintiff without substantial change in the condition in which they were manufactured and sold.

53. Defendant's Darvocet products and their pharmaceutical ingredients in varying dosages were defectively manufactured at the time that they left Defendant's control.

54. The Darvocet products and their pharmaceutical ingredients were unsafe for normal or reasonably anticipated use.

55. Defendant's Darvocet products were unreasonably dangerous in that they were unsafe when used for the intended purpose for medical treatments.

56. The Darvocet products were more dangerous than an ordinary consumer would expect, and the foreseeable risk or injuries from their administration exceeded their associated benefits.

57. Defendant wrongfully permitted defective pharmaceuticals to be placed into the stream of commerce, in the following ways:

a. Defendant failed to exercise reasonable care in the manufacture of their Darvocet products and/or their pharmaceutical ingredients;

b. Defendant failed to exercise reasonable care in the inspection of their Darvocet products and/or their pharmaceutical ingredients;

c. Defendant failed to exercise reasonable care in the packaging of their Darvocet products and/or their pharmaceutical ingredients;

d. Defendant failed to provide any or adequate warnings about the risks and dangers associated with the use of their Darvocet products, as alleged herein and/or their pharmaceutical ingredients;

e. Defendant failed to completely, accurately and in a timely fashion, disclose the adverse event reports associated with the use of their Darvocet products and/or their pharmaceutical ingredients;

f. Defendant failed to recall, withdraw, and remove their Darvocet products and/or their pharmaceutical ingredients from the market once they knew or should have known of the risks and dangers associated with the use thereof;

g. Defendant failed to promptly respond to data, reports, and publications describing problems associated with their Darvocet products and/or their pharmaceutical ingredients by conducting adequate analysis, testing, and surveillance;

h. Defendant failed to implement pre-marketing and post-marketing measures to notify and warn Plaintiff as well as his physicians, medical providers, and other members of the medical community, of the risks and dangers associated with the use of the said Darvocet products and/or their pharmaceutical ingredients, and to recall the defective Darvocet products;

i. Defendant failed to adequately and reasonably establish, maintain, and comport with acceptable quality control mechanisms to prevent defective products from entering the marketplace or from using unsafe ingredients;

j. Defendant failed to comply with and conform to all applicable legal, regulatory, and administrative approval, licensing, and import requirements for the Darvocet products and all component parts, including, but not limited to, the API.

58. Plaintiff could not, through the exercise of reasonable care, have discovered the defects or perceived the dangers posed by the drug.

59. Disregarding continuous findings of the extent of danger posed by Darvocet -containing products, Defendant continued to manufacture design, formulate, produce, and create, make, construct, and/or assemble its Darvocet products to consumers, including Plaintiff.

60. Defendant knew or should have known that consumers such as Plaintiff would foreseeably suffer injury, physically, psychologically, and economically as a result of

Defendant's failure to exercise ordinary care.

61. Plaintiff believes Defendant failed to exercise reasonable care in its production of its Darvocet products. However, even if Defendant is found to have exercised reasonable care in the production of its Darvocet products, Defendant is still liable for the damages and injuries suffered by Plaintiffs pursuant to ORC § 2307.74.

62. As a direct and proximate result of this defective product, Plaintiff has been injured and incurred substantial damages, including, but not limited to, heart arrhythmias, other adverse cardiovascular events, medical and hospital expenses, loss of income, physical and mental pain and suffering, loss of enjoyment of life, and other damages for which Defendants are liable.

SECOND CAUSE OF ACTION
PRODUCT DEFECT IN DESIGN OR FORMULATION
OHIO REVISED CODE § 2307.75

63. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges on information and belief as follows:

64. At all times herein mentioned, Defendant manufactured, designed, formulated, produced, created, made, constructed, and/or assembled Darvocet products use by Plaintiff.

65. Defendant's Darvocet products were defective in that, at the time of release of these products into the stream of commerce by Defendant, the medical benefits of the products were far outweighed by the foreseeable risks associated with the formulation of the products.

66. Defendant's Darvocet products were in an unsafe, defective, and inherently dangerous condition when they were placed by Defendant into the stream of commerce. The dangerous condition of these products was unreasonably dangerous to its users, Plaintiff in

particular.

67. Defendant's Darvocet products were in a defective condition and unsafe, and Defendant knew, had reason to know, or should have known that these products were defective and unsafe, even when used as prescribed by Defendant and prescribing physicians.

68. The nature and magnitude of the risk of harm associated with the design and formulation of Defendant's Darvocet products, including, but not limited to, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, is high in light of the intended and reasonably foreseeable uses of the products.

69. The formulation of Defendant's Darvocet products is more dangerous than a reasonably prudent consumer would expect when used in the intended or foreseeable manner. These products were more dangerous than Plaintiff expected.

70. The benefits of Defendant's Darvocet products do not outweigh the risks.

71. A practical and medically feasible alternative drug was available for Plaintiff that would have prevented the harm for which Plaintiff suffered and remedied the pain for which Plaintiff consumed Defendant's Darvocet product.

THIRD CAUSE OF ACTION
PRODUCT DEFECT DUE TO INADEQUATE WARNING AND/OR INSTRUCTION
OHIO REVISED CODE § 2307.76

72. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further allege on information and belief as follows:

73. Defendant had a duty to warn Plaintiff of the risks associated with consuming Defendant’s Darvocet-containing products; namely, that these products may cause heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death. Defendant knew or should have known about these risks.

74. Defendant failed to provide adequate warnings or instruction that a drug manufacturer, exercising reasonable care, would have provided concerning these risks and other health concerns for which Plaintiff as suffered.

75. Defendant's Darvocet-containing products are defective due to inadequate post-marketing warning or instruction.

76. By reason of the foregoing, the Defendant is liable to the Plaintiff for the manufacturing, designing, formulating, producing, creating, making, constructing, and/or assembling the Darvocet products which are defective due to inadequate warning or instruction.

FOURTH CAUSE OF ACTION
PRODUCT DEFECT IN FAILURE TO CONFORM TO REPRESENTATIONS
OHIO REVISED CODE § 2307.77

77. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further allege on information and belief as follows:

78. Prior to the time that the defective Darvocet was administered to Plaintiff, Defendant expressly warranted to Plaintiff, his medical providers and/or agents, that the Darvocet products and their pharmaceutical ingredients were of merchantable quality and safe for the use for which they were intended.

79. At the time of making said representations, Defendant had actual and/or constructive knowledge that the Darvocet products to be used were not fit, safe, effective and proper for such purposes.

80. Plaintiff and his medical providers relied upon the skill, judgment and representations of Defendant in their Darvocet administration.

81. These representations were untrue, misleading, and inaccurate at the time

Defendant made them.

82. Defendant knew that the Darvocet products were unsafe for their intended use and were not of merchantable quality as represented by Defendant in that they had dangerous propensities when put to their intended use, would cause severe injury to the user, and did in fact cause such injury.

83. The Darvocet products, designed, manufactured, distributed, fabricated, packaged, compounded, merchandised, advertised, promoted, supplied, and/or sold by Defendant, proximately and directly caused Plaintiff to be injured and to incur substantial damages, including, but not limited to, medical and hospital expenses, loss of income, physical and mental pain and suffering, loss of enjoyment of life, and other damages for which Defendant is liable.

84. Defendant marketed its Darvocet products as a safe, less addictive, and less potent alternative to the widely used codeine, and as being an option for individuals who were suffering from moderate pain as opposed to severe. Defendant's Darvocet products were neither safe nor less addictive.

85. While Plaintiff believes and avers that Defendant acted negligently and recklessly in making the representations, in the event Defendant is not found to have acted negligently or recklessly, Defendant is still liable for the damages and injuries suffered by Plaintiffs pursuant to ORC § 2307.77.

86. Defendant's conduct was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety to patients/consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

FIFTH CAUSE OF ACTION
LOSS OF CONSORTIUM

88. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further allege on information and belief as follows:

89. As a direct and proximate result of Defendant's wrongful conduct detailed above, Plaintiff DORIS DAUGHERTY, spouse of Plaintiff JAMES DAUGHERTY, was deprived of the care, consideration, compassion, consortium and concern of Plaintiff JAMES DAUGHERTY, and has suffered injuries and damages thereby.

90. Plaintiff DORIS DAUGHERTY is thereby entitled to an award of damages for loss of consortium.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against the Defendants, jointly and severally, as follows:

A. For an award of compensatory damages, including damages against Defendant for past and future damages, medical and hospital expenses, loss of income, loss of consortium, pain and suffering, medical monitoring and other damages according to proof at trial, but believed to be in an amount greater then $75,000.00.

B. For an award of punitive or exemplary damages against Defendant for the wanton, willful, fraudulent, reckless acts of Defendant who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiff in an amount sufficient to punish and deter future similar conduct.

C. For reasonable attorneys' fees and costs;

D. For pre-judgment interest; and

E. For such further and other relief the court deems just, equitable, and proper.

JURY DEMAND

Plaintiff respectfully demands a trial by jury on all issues so triable.

Respectfully submitted,

/s/ John R. Climaco

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